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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/673,934

09/30/2003

Volkert A. Zeijlemaker

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EXAMINER

ALTER, ALYSSA M

ART UNIT

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/673,934	<b>Applicant(s)</b> ZEIJLEMAKER ET AL.	
	<b>Examiner</b> ALYSSA M. ALTER	<b>Art Unit</b> 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 38 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 30, 2008 has been entered.

### ***Election/Restrictions***

Newly submitted claim 38 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

Inventions I (claims 1-37) and II (claims 38) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation. Invention II requires the use of an external programmer, while Invention I does not.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 38 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

***Response to Arguments***

Applicant's arguments with respect to claims 1-37 have been considered but are not persuasive. Additionally the claims are rejected with new ground(s) of rejection under by Tsitlik et al. (US 5,217,010).

The Applicant argued that Axel et al. does not “adjusting telemetry of a medical device during a period when the electromagnetic radiation bursts are being applied to the patient based on information associated with MRI bursts so that the medical device is capable of transmitting information by telemetry during the period when bursts are being applied.”

However, the Axel et al. discloses the communication of an ECG signal while the patient is undergoing an MRI. Thus, the communication is adjusted based on the information associated with the MRI bursts.

Furthermore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., “adjusting telemetry of a medical device during a period when the electromagnetic radiation bursts are being applied to the patient based on *information associated with MRI bursts so that the medical device is capable of transmitting information by telemetry during the period when bursts are being applied*) are not recited in all of the rejected claims, but only claims 1-8. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claims 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are vague and appear to be method claims since it provides no further structure, but a mere recitation of intended use for such structure.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

1. Claims 1-5, 8-9, 11-16, 20-21, 24-26, 30, 32 and 34-37 stand rejected under 35 U.S.C. 102(e) as being anticipated by Axel (US Patent Publication 20040073124 A1). Axel discloses ECG detection system for a patient undergoing an MRI. The “ECG information is signal is digitized (for example at 250 Hz) and recorded on a workstation, laptop, or other PC computer with a commercial interface program” (page 7, paragraph

73). Therefore, since the ECG information is sent to a workstation, laptop, or other PC computer, the information is transmitted by telemetry during the MRI treatment. Since telemetry, is the transmission of data, by wire or other means to a remote source, the ECG information sent to a workstation, laptop or other PC computer constitutes telemetry. Furthermore, since the communication of an ECG signal occurs while the patient is undergoing an MRI, the communication is thus adjusted based on the information associated with the MRI bursts.

As to claims 2-5, 11-12, 14-16 and 24, "When the real-time ECG signal exceeds a threshold, a trigger is sent to the MRI machine to initiate a type of data acquisition. By way of example, the system could send a 5 volt internal or external trigger input to the MRI machine. Once the MRI machine receives the trigger input, the MRI machine initiates the data acquisition"(page 5, paragraph 58).

As to claim 8, "as a patient undergoes MRI, the magnet in the MRI machine causes blood flow-induced voltage potentials which interfere with the QRS complex component of the ECG signal. To minimize the effect of interference patterns on detection of the QRS complex, the present invention takes an ECG signal from a patient and uses this ECG signal to detect the shape in time unique to QRS complex in the patient undergoing analysis" (page 3, paragraph 36). The examiner considers the blood-induced voltage potentials to be an identification of MRI magnetic gradients.

As to claims 9 and 13, since the MRI is in communication with a workstation, laptop, or other PC computer, the telemetry is adjusted for effective communication during a period of electromagnetic radiation bursts.

2. Claims 1-2, 8-11, 13-14, 20-23 and 25-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Tsitlik et al. (US 5,217,010). Tsitlik et al. discloses an implantable pacemaker for use during an MRI. "Since the implantable pacemaker shown in FIG. 3 is enclosed in an RF shield, it was necessary to develop a unique method of external programming. The external programmer 52 works in a conventional manner. However, the information received by the pacemaker 50 is processed to separate the desired communication signal from the RF signals produced by the MRI system. An antenna 70 is connected to the telemetry RF amplifier 72 via the telemetry receiver/band pass filter 74. This filter is a band pass filter that passes only the specific programming frequency, currently approximately 100-200 kHz, to the telemetry amplifier 72. An algorithm in the telemetry logic circuit 76 interprets all RF received by the telemetry antenna 70 and will only allow programming of the pacing logic circuit 54 when a specific telemetry enable pattern is received. The telemetry enable logic circuit 76 will also inhibit control of the pacing output stage 58 while programming is taking place. This prevents improper and potentially dangerous pacing parameters from controlling the pacing stage" (col. 9, lines 49-68).

Therefore, since the "information received by the pacemaker 50 is processed to separate the desired communication signal from the RF signals produced by the MRI system" the system thus modifies the telemetry of the device during a period when MRI bursts are occurring.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 3-4, 12, 15-16 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Tsitlik et al. (US 5,217,010). Tsitlik et al. disclose an implantable pacemaker for use during an MRI. Additionally, since the device of Tsitlik et al. filters out the frequencies from the MRI bursts the system necessarily senses the time between the burst.

In the alternative, although the examiner considers Tsitlik et al. to disclose the determination of time intervals above, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the device of Tsitlik et al. with the determination of time intervals in order to provide the predictable results of ensuring that the filtering is occurring at a time when the burst are being applied. Furthermore, such timing can be used as a reference for the physician or technician operating the MRI machine.

2. Claims 5-7, 17-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tsitlik et al. (US 5,217,010). Tsitlik et al. discloses the claimed invention except for the increasing power of telemetry signals. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the power of the telemetry signals, since it has been held that where the general conditions of a claim



are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05). Therefore, if the signals were too weak to communicate during the bursts it would be obvious to increase the power to provide for effective communication. Furthermore, such a modification to components operation (i.e, disabling one or more components) would provide the predictable results of improving the transmission power, which is well known in the art.

As to claims 7, Tsitlik et al. discloses the claimed invention except for the selection of packet size. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the packet size, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05). Therefore, selecting the packet size that provides for effective communication would have been obvious to one having ordinary skill in the art.

3. Claims 6-7, 10, 17-19, 22-23, 27-29, 31 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Axel (US Patent Publication 20040073124 A1). Axel discloses the claimed invention except for the selection of packet size. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the packet size, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05). Therefore, selecting the packet size that provides for effective communication would have been obvious to one having ordinary skill in the art.

As to claims 6, 10, 17-18 and 22-23, Axel discloses the claimed invention except for the increasing power of telemetry signals. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the power of the telemetry signals, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233 (see MPEP 2144.05). Therefore, if the signals were too weak to communicate during the bursts it would be obvious to increase the power to provide for effective communication. Furthermore, such a modification to components operation would provide the predictable results of improving the transmission power, which is well known in the art.

As to claims 27-29, 31 and 33, Axel discloses the claimed invention except for the implantable medical device. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the ECG signal detection means as taught by Axel with an implantable medical device since it was known in the art to employ implantable medical devices to determine ECG signals.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALYSSA M. ALTER whose telephone number is (571)272-4939. The examiner can normally be reached on M-F 9am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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